

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Patent Application No. 10/568,995

Applicant: Hill et al.

Filed: February 21, 2006

TC/AU:

Examiner:

Docket No.: 250898 (Client Reference No. 12417US2-PDW/SJR)

Customer No.: 23460

Mail Stop PCT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 CFR 1.97 and 1.98, the references listed on the enclosed Form PTO-1449 and/or Substitute Form PTO-1449 ("Form 1449") are submitted for consideration by the Examiner in the examination of the above-identified patent application.

The full consideration of the references in their entirety by the Examiner is respectfully requested and encouraged. Also, it is respectfully requested that the references be entered into the record of the present application and that the Examiner place his or her initials in the appropriate area on the enclosed Form 1449, thereby indicating the Examiner's consideration of each of the references.

The submission of the references listed on the Form 1449 is for the purpose of providing a complete record and is not a concession that the references listed thereon are prior art to the invention claimed in the patent application. The right is expressly reserved to establish an invention date earlier than the above-identified filing date in order to remove any reference submitted herewith as prior art should it be deemed appropriate to do so.

Further, the submission of the references is not to be taken as a concession that any reference represents art that is relevant or analogous to the claimed invention. Accordingly, the right to argue that any reference is not properly within the scope of prior art relevant to an examination of the claims in the above-identified application is also expressly reserved.

The Information Disclosure Statement is being filed:

- ☒ **within** any one of the following time periods: (a) within three months of the filing date of a national application other than a continued prosecution application under 37 CFR 1.53(d); (b) within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 of an international application; (c) before the mailing date

of a first Office Action on the merits; or (d) before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

- ☐ **after** (a), (b), (c) or (d) above, but before the mailing date of a final action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and includes *one* of:
- ☐ the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below).
- or*
- ☐ the fee of \$180 set forth in 37 CFR 1.17(p) (see "Fees" below).
- ☐ **after** the mailing date of a final action under 37 CFR 1.113 or a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and on or before payment of the issue fee, and includes the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).
- ☐ **after** the mailing date of a Notice of Allowance under 37 CFR 1.311, and on or before payment of the issue fee, and **within** thirty days of receiving each item of information contained in the Information Disclosure Statement, and includes the Statement under 37 CFR 1.704(d) (see "Statement under 37 CFR 1.704(d)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).

NOTE: This is for original applications except applications for a design patent, filed on or after May 29, 2000, wherein a paper containing only an Information Disclosure Statement in compliance with 37 CFR 1.97 and 1.98 is being filed.

### Copies of the References

- ☒ Copies of all of the references listed on the enclosed Form 1449 are enclosed herewith.
- ☐ Copies of U.S. patents and patent applications that are listed on the accompanying Form 1449 are not enclosed herewith. Copies of other references identified on the accompanying Form 1449 are enclosed herewith.
- ☐ Attached to each reference not in the English language is a concise explanation of the relevance pursuant to 37 CFR 1.98(a)(3). An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of the relevance pursuant to 37 CFR 1.98(a)(3).
- ☒ A copy of the foreign search report is enclosed herewith.
- ☐ The references listed on the enclosed Form 1449 were previously identified in the parent application(s) of the present application, and copies of the references were furnished at that time. Accordingly, additional copies of the references are not

submitted herewith, so as not to burden the file with duplicate copies of references. The Examiner is respectfully requested to carefully review the references in accordance with the requirements set out in the Manual of Patent Examining Procedure. In accordance with 37 CFR 1.98(d), the details of the parent application(s) relied upon for an earlier filing date under 35 USC 120 in which copies of the references were previously furnished are set out below:

U.S. APPLICATIONS		STATUS (check one)		
U.S. APPLICATIONS	U.S. FILING DATE	PATENTED	PENDING	ABANDONED
1.				
2.				
3.				

**Statement under 37 CFR 1.97(e)**

- ☐ The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.
- ☐ The **undersigned** hereby states that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

**Statement under 37 CFR 1.704(d)**

- ☐ The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

**Fees**

- ☒ **No fee** is owed by the applicant(s).
- ☐ Charge Deposit Account No. 12-1216 in the amount of **\$180.00** (37 CFR 1.17(p)).  
(A duplicate copy of this communication is enclosed for that purpose.)


In re Appln. of Hill et al.  
Application No. 10/568,995

**Authorization to Charge Additional Fees**

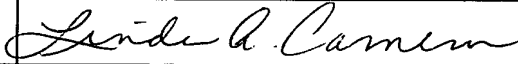
- ☒ If any additional fees are owed in connection with this communication, please charge Deposit Account No. 12-1216. (A duplicate copy of this communication is enclosed for that purpose.)

**Instructions as to Overpayment**

- ☒ Credit Account No. 12-1216.  
☐ Refund

  
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Date: October 12, 2006

<b>MAILING/TRANSMISSION CERTIFICATE UNDER 37 CFR 1.8 OR 1.10</b>			
I hereby certify that this document and all accompanying documents are, on the date indicated below, being <input checked="" type="checkbox"/> deposited with the U.S. Postal Service using "Express Mail" service in an envelope addressed in the same manner indicated on this document with Express Mail Label Number EV419251412US, <input type="checkbox"/> deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed in the same manner indicated on this document, or <input type="checkbox"/> facsimile transmitted to the U.S. Patent and Trademark Office at fax number: (571) 273-8300.			
Name (Print/Type)	Linda A. Cameron		
Signature		Date	October 12, 2006

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Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)			<b>Complete if Known</b>		
			Application Number	10/568,995	
			Filing Date	February 21, 2006	
			First Named Inventor	HILL	
			Group Art Unit		
Examiner Name					
Sheet	1	of	1	Attorney Docket Number	250898

FOREIGN PATENT DOCUMENTS								
Examiner Initials	Doc. No.	Foreign Patent Document			Name of Patentee or Applicant	Date of Publication	Translation	
		Office	Application or Patent Number	Kind Code			Yes	No**
	AA	WO	00/44785	A1	Hoffmann-La Roche Inc.	8/3/2000		

OTHER - NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Doc. No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Translation		
			Yes	No**	
	A B	ARPINATI, M., et al., <i>Granulocyte-Colony Stimulating Factor Mobilizes T Helper 2-Inducing Dendritic Cells</i> , Blood (2000), 95(8), 2484-2490			
	A C	DE HAAN, G., et al., <i>Efficient Mobilization of Haematopoietic Progenitors After a Single Injection of Pegylated Recombinant Human Granulocyte Colony-Stimulating Factor in Mouse Strains with Distinct Marrow-Cell Pool Sizes</i> , British Journal of Haematology (2000), 110:638-646			
	A D	LI, E.C., <i>Pegfilgrastin</i> , Journal of the Pharmacy Society of Wisconsin, May/June 2003, 34-39			
	A E	MOLINEUX, G., et al., <i>A New Form of Filgrastim with Sustained Duration in Vivo and Enhanced Ability to Mobilize PBPC in Both Mice and Humans</i> , Experimental Hematology (1999), 27:1724-1734			
	A F	MORRIS, E.S., et al., <i>Donor Treatment with Pegylated G-CSF Augments the Generation of IL-10 Producing Regulatory T Cells and Promotes Transplantation Tolerance</i> , Blood, 1 May 2004, 103(9):3573-3581			
	A G	PAN, L., et al., <i>Pretreatment of Donor Mice With Granulocyte Colony-Stimulating Factor Polarizes Donor T Lymphocytes Toward Type-2 Cytokine Production and Reduces Severity of Experimental Graft-Versus-Host Disease</i> , Blood (1995), 86(12):4422-4429			
	A H	PAN, L., et al., <i>Granulocyte Colony-Stimulating Factor-Mobilized Allogeneic Stem Cell Transplantation Maintains Graft-Versus-Leukemia Effects Through a Perforin-Dependent Pathway While Preventing Graft-Versus-Host Disease</i> , Blood, Vol. 93, No. 12 (June 15) 1999: pp. 4071-4078			
	A I	WILLIS, F., et al. <i>Pegfilgrastim</i> , Expert Opinion on Biological Therapy (2002), 2(8):985-992			
	A J	YAMASAKI, M., et al., <i>Modification of Recombinant Human Granulocyte Colony Stimulating Factor (rhG-CSF) and its Derivative ND28 with Polyethylene Glycol</i> , Journal of Biochemistry (1994), 115:814-819			

Examiner Signature		Date Considered	
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\* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

+ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).